February 22, 2018

SeaSpine Orthopedics Corporation
Ms. Gina Flores
Senior Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K173334
Trade/Device Name: SeaSpine Spinous Process System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: January 26, 2018
Received: January 29, 2018

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173334

Device Name
SeaSpine Spinous Process System

Indications for Use *(Describe)*

The SeaSpine Spinous Process System is a posterior non-pedicle supplemental fixation system intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions:

• Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal tumor

The Spinous Process device is not intended for stand-alone use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

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Phone number: (760) 216-5136
Fax number: (760) 683-6874

Contact person: Gina Flores, Sr. Regulatory Affairs Specialist
Email address: gina.flores@seaspine.com

Date Prepared: February 21, 2018

Device Name

Trade Name: SeaSpine Spinous Process System

Common Name: Spinous Process Plate

Classification Name: Spinal Interlaminal Fixation Orthosis

Classification: 21 CFR 888.3050, Spinal Interlaminal Fixation Orthosis

Class: II

Product Code: PEK

Legally Marketed Predicate Device

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate			
K121924	PEK	SeaSpine Spinous Process System	SeaSpine Orthopedics Corporation
Additional Predicates			
K071877, K121316	KWP, MNI	Aspen MIS Fixation System	Zimmer/Biomet (formerly Lanx, Inc.)
K141317	PEK	Aurora Spine ZIP Flared System	Aurora Spine, Inc.

Device Description

The SeaSpine Spinous Process System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). The Spinous Process System consists of an implantable spacer featuring 2 plates (male and female) with a variable barrel width, fixed wing length, and fixed plate width, and set screws that clamp bilaterally to the spinous processes. Each plate contains spikes (teeth) for fixation to the spinous process to aid in resisting

rotation, flexion, and extension after implantation. Implants are available in a range of sizes to suit the individual pathology and anatomical conditions of the patient, and manufactured from Ti-6Al-4V ELI per ASTM F136.

Intended Use/Indications for Use

The Spinous Process System is a posterior non-pedicle supplemental fixation system intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal tumor

The Spinous Process device is intended for stand-alone use.

Summary of Technological Characteristics

The Spinous Process System and predicate device have the same operational principle; they are spacers that engage the spinous processes and provide fixation during fusion.

The SeaSpine Spinous Process System is substantially equivalent to the cited predicate devices in areas including intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

The subject and predicate device are based on the following similar technological elements:

- Plate lengths
- Plate widths
- Barrel lengths and widths
- Same implant materials, Titanium Alloy (6AL-4V ELI per ASTM F136)
- Utilize the same set screw

Non-Clinical Testing

Static axial compression, static axial torsion, and dynamic axial compression bending tests were performed using methods based on ASTM F1717 and ASTM F2624. The testing demonstrated substantially equivalent mechanical performance as compared to the predicate.

Clinical Testing

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

Conclusions

The submitted data demonstrate that the SeaSpine Spinous Process System is as safe, as effective, and performs at least as safely and effectively as the cited legally marketed predicate devices.